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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,595	04/16/2004	Mark A. Hoffman	CRNC	1203

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SHOOK, HARDY & BACON L.L.P.
Intellectual Property Department
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EXAMINER	
MORAN, MARJORIE A	
ART UNIT	PAPER NUMBER
1631	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/08/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/826,595	HOFFMAN ET AL.	
	Examiner	Art Unit	
	Marjorie A. Moran	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-51* is/are pending in the application.

4a) Of the above claim(s) *8,9,17,25,26,34,42,43 and 51* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,10-16,18-24,27-33,35-41 and 44-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Election/Restrictions

Applicant's election of a clinical action which is a warning in the reply filed on 11/13/06 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 8, 9, 17, 25, 26, 34, 42, 43, and 51 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 11/13/06.

An action on the merits of claims 1-7, 10-16, 18-24, 27-33, 35-41, and 44-50, as they read on the elected species, follows.

Drawings

New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because portions of Figures 3-5 are so dark that it is impossible to determine what is being shown. Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7, 10-16, 18-24, 27-33, 35-41, and 44-50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 18, and 35 recite a step/component of comparing a genetic test result value to a list of polymorphism values "associated with an atypical clinical event." Earlier steps had associated a gene with a clinical agent. It is unclear whether the "atypical clinical event" is also intended to be associated with the clinical agent, or only with the polymorphism value. It is noted that multiple polymorphism/gene values may be associated with a single clinical agent, and that multiple clinical agents may be associated with a single polymorphism, thus an "atypical clinical event" associated with a polymorphism value is not necessarily one which is also associated with a particular clinical agent. As the intended limitation is not clear, the claims are indefinite. Claims 2, 3, 10, 11-16, 19, 20, 27-33, 36, 37, and 44-50 depend from one of claims 1, 18,, or 35 and fail to clarify the limitation, and are therefore also indefinite.

Claims 5, 22, and 39 limit a plurality of genes to have particular properties. It is unclear what limitation of the claimed METHOD or device (for performing a method) is intended by limiting genes to have one or more variants, particularly when the parent claims recite determining if a gene (singular) is associated with clinical information, and obtaining a genetic test result value (singular) for the gene. If applicant intends that

association, etc. be performed for multiple genes, then this is not clearly recited. As the limitation(s) intended in claims 5, 22, and 39 are unclear, the claims are indefinite.

Claim 10 recites that a genetic test result value "is obtained" from an electronic medical record. It is unclear whether applicant intends a method step; i.e. one of obtaining the record, or intends a limitation of the genetic test result value. If the former, then applicant is reminded that method steps should be recited in active, positive format. IF the latter, then it is further unclear what limitation of the method is intended by reciting a source of data.

Claims 27 and 44 recite that a genetic test result value "is obtained" from an electronic medical record. As the claims are directed to products, it is unclear what limitation of the product is intended by reciting an apparent method step. If applicant intends a limitation of the genetic test result value, then it is further unclear what limitation of the product is intended by limiting data.

Claims 11-13, 28-30, and 45-47 recite a "second data structure." As no "first data structure" is recited in any of parent claims 1, 18, and 35, it is unclear what is intended by a "second data structure." It is noted that the parent claims recite a "list" of polymorphism values; however, a list is not generally considered a "data structure." As the limitation intended is unclear, the claim is indefinite.

Claim 14 recites that first and second data structures "are integrated" as a single data structure. IT is unclear if applicant intends a method step; i.e. one of integrating data structures, or intends a limitation of the data and/or data structures. If the former, then applicant is reminded that method steps should be recited is active,

positive terms. If the latter then it is noted that the limitation is nonsensical as the claim appears to limit two different data structures (first and second) to be a single data structure. It is noted that a single data (integrated) structure may COMPRISE two (smaller or disparate) data sets, but the claim does not clearly set forth such a limitation. As the limitation is intended is unclear, the claim is indefinite.

Claims 31 and 48 recite that first and second data structures "are integrated" as a single data structure. As the claims are directed to products, it is unclear what limitation of the product is intended by reciting an apparent method step. If applicant intends a limitation of the data and/or data structures, then it is noted that the limitation is nonsensical as each claim appears to limit two different data structures (first and second) to be a single data structure. It is noted that a single data (integrated) structure may COMPRISE two (smaller or disparate) data sets, but the claims do not clearly set forth such a limitation. As the limitation intended is unclear, the claims are indefinite.

Claims 15, 32, and 49 recite the limitation "the patient specific risk" each in line 2. There is insufficient antecedent basis for this limitation in the claim. Parent claims 1, 18 do not recite either a patient or a risk of anything, therefore there is no antecedent basis for either a "specific patient" or a "specific risk TO a patient" in the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-7, 10-16, 18-24, 27-33, 35-41, and 44-50 a are rejected under 35 U.S.C. 103(a) as being unpatentable over HOGAN (US 2002/0110823, filed 7/11/00) in view of USAMI et al. (J. Human Genetics (1999) vol. 44/5, pp. 304-307).

HOGAN teaches a method of preventing adverse reactions to operative and post-operative drugs (agents) comprising receiving/obtaining data about clinical agents, and whether the clinical agents are associated with one or more genes (para's 117 and 136), as in claims 1, 18, and 34. HOGAN teaches comparing genetic test result values for multiple genes to polymorphism values associated with adverse reactions; i.e. risks associated with atypical clinical events (para's 186, 115, 129, and 136-147), and teaches that "agent information" may include dosage and other PK/PD parameters (para 129), as in claims 1, 2, 4, 5, 11, 12, 14, 16, 18, 19, 21, 22, 28, 29, 31, 33, 35, 36, 38, 39, , 45, 46, 48, 50. HOGAN teaches outputting information about the atypical clinical event associated with the polymorphism value(s) such that a "clinical action"

may be initiated (para's 190-191), as recited in claims 6, 13, 23, 30, 40, and 47. HOGAN teaches that clinical agent and genetic information may be stored and communicated via various computerized applications, including electronic medical records (para's 186 and 188), thus making obvious a computer system and computer readable medium for performing his analysis, as recited in claims 3, 10, 20, 27, 37, and 44.

Although HOGAN teaches that his agents cause adverse clinical reactions (para 126), he does not specifically teach that his output is a "warning" that an agent should not be administered.

USAMI teaches that where a person is known to have a polymorphism indicating an adverse reaction to a clinical agent, a warning is initiated that the person should not be administered the agent (p. 306).

It would have been obvious to one of ordinary skill in the art to have initiated a warning in the method, system and medium of HOGAN that an agent should not be administered, as taught by USAMI, where the motivation would have been to save lives and prevent adverse reactions to the agent, as taught by both HOGAN (para's 126 and 194) and USAMI (pp. 306-307: Discussion).

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (571)

272-0720. The examiner can normally be reached on Monday-Friday; 6 am-2:30 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571)272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Marjorie A. Moran
Primary Examiner
Art Unit 1631

Marjorie A. Moran
2/4/07